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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,711 04/05/99 SAKAI

T 1/F3511PTUS

HM22/0425

EXAMINER

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WASHINGTON DC 20006

WANG, S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED:

04/25/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/269,711	SAKAI ET AL.
	Examiner	Art Unit
	Shengjun Wang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,3-9 and 11-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,3-9 and 11-20 is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
    1. received.
    2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- |  |  |
|--|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Amendments Objection*

1. The amendments filed on April 5, 1999 and September 13, 1999 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) deletion of the content related to anticancer including the deletion in: page 1, line 4, page 2, line 16; page 3, line 2, lines 8-11, lines 24 and 25, page 4, lines 1 and 2; page 9, line 19, page 11, line 19, page 13, line 23-24, page 15, lines 8-11; pages 18 and 19, page 20, lines 1-9, lines 22-24, page 25, lines 22-24, page, 26, lines 3-10, page 27, lines 2-4, 8-9, page 28, lines 1-2, page 36, lines 15-16, page 37, lines 8-9, page 38, lines 24-25, page 40, lines 16-17, page 41, lines 22-23, page 42, lines 21-22, page 43, lines 21-22, page 45, lines 1-2, page 64, lines 3-4;
- b) addition of the limitation of “provided that they /it are/is free from phosphate ester and phosphonate ester in molecular structure” on page 7 and “free from phosphate ester and phosphonate ester in molecular structure” on page 3, and in claims 1 and 9; deletion of the listed phosphate and phosphonate compound on page 10.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicants' remarks submitted April 5, 1999 and September 13, 1999 regarding the amendments discussed above have been considered but are not persuasive since it is unclear that applicant had possession of the invention by their effective US filing date. Submission of a translated English copy of the international application herein as filed Oct. 31, 1997 showing

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support for the amendments above would be persuasive to remove the objection above and rejection below for new matter.

***Claim Rejections 35 U.S.C. – 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed inventions exclude the presence of phosphate ester and phosphonate ester in the compositions. This is not supported by the original disclosure as discussed in the new matter objection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3-7 recites the limitation "agents". There is insufficient antecedent basis for this limitation in the claim. Note that claim 1 is drawn to a single agent.

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***Claim Rejections 35 U.S.C. - 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.  
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nojima et al. (AA), JPO abstract provided herewith, or Yazawa et al. (AB) JPO abstract provided herewith.

Nojima et al. teach a composition comprising glycerolipid as the active component for treating cancer. See the abstract. Yazawa et al. teach a composition comprising glyceroglycolipid as the active components for treating or preventing cancer.

7. Claims 1, 3-5, 7-8 and 17-18 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Winget (US Patent No. 5,767,095).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget also teaches that purity of the glyceroglycolipid is important, i.e., the glyceroglycolipid should be free from other compounds, e.g., phospholipid. See column 1, lines 29-40, particularly, column 1, line 32.

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***Claim Rejections 35 U.S.C – 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6, 11-16 and 19-20 rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,767,095) and Yazawa et al. (AB) JPO abstract provided herewith, in view of Wright et al. (CAPLUS Abstract, 1980:74554) and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget further teaches that glyceroglycolipid is present in many food products, e.g., lettuce, broccoli, wheat, etc. See column 1, 19-22. Yazawa et al. teach a composition comprising glyceroglycolipids as the active components for treating or preventing cancer.

The primary references do not teach expressly the employment of glyceroglycolipid in food and beverage products. The primary references do not teach the employment of acid and/or base in the process of making the glyceroglycolipid.

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However, Wright et al. teach that tea comprises glyceroglycolipid, suggesting that glyceroglycolipid may be consumed in a beverage. See the abstract. Nelson teach that acid treatment of materials containing lipid is a well known technique for lipid separation and purification. See page 45.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glyceroglycolipid in food or beverage products and to employ acid treatment in the process of making the glyceroglycolipid.

A person of ordinary skill in the art would have been motivated to employ glyceroglycolipid in food or beverage products because glyceroglycolipids are known to be useful for treating or preventing cancer and are known to be present in many food and beverage products. The employment of glyceroglycolipid in food or beverage products is reasonably expected to be beneficial for maintaining health. Furthermore, the employment of acid/base treatment in the process of making the glyceroglycolipid is seen to be obvious since the separation/purification of prior art glyceroglycolipids would be expected to increase the concentration of the active glyceroglycolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation. Note that intended use "apoptosis induction" does not further limit claims drawn to a composition. See, e.g., In re Hack 114 USPQ 161.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

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April 3, 2000

  
MINNA MOEZIE  
PRIMARY EXAMINER